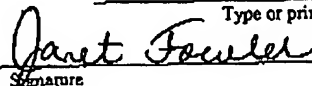


JUN 13 2005

CERTIFICATION OF FACSIMILE TRANSMISSION	
I hereby certify that this paper is being facsimile transmitted to the Patent and Trademark Office on the date shown below to 703-872-9306	
Janet Fowler Type or print name of person signing certification	
 Signature	June 13, 2005 Date

**PATENT APPLICATION**  
**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant	: James Arthur Hoffmann	)	
Serial No.	: 10/072,540	)	
Filed	: February 8, 2002	)	Group Art Unit:
For	: GLP-1 Formulations	)	1614
Docket No.	: X-11368A	)	Examiner:
		)	Delacroix-Muirheid

**COMMUNICATION**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

On 6 June 2005, Applicant filed a Request for Continued Examination under 37 C.F.R. § 1.114 of U.S. Serial No. 10/072,540. In response to the Final Rejection (Paper No. 122804) dated January 11, 2005, Applicant also submitted a response, an amended IDS form 1449, and a Declaration under 37 C.F.R. § 1.131 from the inventor and Applicant, James Arthur Hoffman. In addition, a petition for a two-month extension of time under 37 C.F.R. § 1.136 was also included in the mailing.

It has come to my attention that Exhibit A (that was to accompany the Declaration of Applicant James Hoffmann) was inadvertently omitted from this case.

Serial No. 10/072,540

Applicant respectfully requests that the Examiner enter the Exhibit A into the 6 June 2005 Declaration. If for any reason, the Examiner feels a telephone conversation would be helpful, the Examiner is urged to call me.

Respectfully submitted,



Gregory A. Cox  
Attorney for Applicant  
Registration No. 47,504  
Phone: 317-276-0280

Eli Lilly and Company  
Patent Division/GAC  
Lilly Corporate Center  
Indianapolis, Indiana 46285

June 13, 2005

Project No. E2BBook No. LIA

71

VE-62-1 Formulations + Additives

Procedure: For each excipient that allows VE-62-1 (7.57) to stay clear in formulations with 3.15 mg/ml m-cresol at pH 6.75 at RT and 4°C.

Procedure: VE-62-1 (7.57) was prepared at (mg/ml) 16 mg/ml (by weight) in 100m sodium phosphate Tris buffer - 16 mg/ml m-cresol (pH 6.75) adjusted to pH 6.00 with 2N HCl. m-cresol used at 100 mg/ml is ethanol.

For each sample below to 500 µl of VE-62-1 solution was added the minimum before 30-60 at RT. 15 µl of the m-cresol solution was added. Mix and store at RT 2-4 hr.

ESA-71

Solvent

Additive

w/ m-cresol  
Stay Clear  
at RT?

V	10 µl Tween 40	OK	Yes
W	10 µl Tween 80	OK	Yes To Page No. 7
Witnessed by me,	Date	Invented by James A. Hoffmann	Date 3/6/97
		Recorded by T. A. Hoffman	

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72

Project No. 628Book No. 178URE-18-628-1 / m-cresol Emulsions + Additives

From Page 68

Procedure cont.

All samples that remained clear at RT during the day (2-4 hr) were covered with parafilm and placed in the refrigerator (4°C).

Two more samples were made up later in the day:

Sample	Additive	at RT	at 4°C
X	1ml Tween 40	OK	Almost
Y	1ml Tween 80	OK	No

Sample Y had a lot of biomass and precipitates came right away, while sample X had only a trace of biomass after 45 min at RT.

After overnight at 4°C, all solutions that had remained clear at RT were checked. None was totally clear, although sample W was almost clear.

Results: several additives in the URE-18-628-1 / m-cresol / glycerin emulsion help maintain clarity at RT.

and 2% Tween. At these levels though, none of the additives was able to keep the emulsion clear at 4°C overnight in the refrigerator.

On rewarming to RT, all samples reclarified pretty readily.

The aggregation phenomenon at 4°C leads to biomass that appears to be reversible.

Conclusions: several additives

(2% Tween 40 or 80) improve solubility of URE-18-628-1 in emulsions with m-cresol and glycerin at RT, especially at ambient temperature.

Witnessed &amp; Understood by me,

Date

Invented by James A. Hoffmann

Date

Recorded by

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